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UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

UNITED STATES OF AMERICA, Plaintiff, v. EVIG, LLC d/b/a BALANCE OF NATURE, a corporation, and DOUGLAS LEX HOWARD, an individual, Defendants.	[PROPOSED] CONSENT DECREE FOR PERMANENT INJUNCTION Case No. 4:23-cv-00089-DN Judge David Nuffer
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Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction (the “Complaint”) against Evig, LLC doing business as Balance of Nature (“Evig” or “the company”), a corporation, and Douglas Lex Howard, individual (collectively, “Defendants”), and Defendants, without admitting or denying the allegations in the Complaint, having appeared and consented to entry of this Consent Decree of Permanent Injunction (the “Decree”) without contest and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action.
2. The Complaint states a cause of action against Defendants under the Federal Food,

Drug, and Cosmetic Act (the “Act”), 21 U.S.C. § 301 *et seq.*

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food, namely dietary supplements, as defined by 21 U.S.C. § 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of the current good manufacturing practice regulations for dietary supplements set forth in 21 C.F.R. Part 111 (“Dietary Supplement CGMP”).

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drugs, as defined in 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use.

5. The Complaint alleges that Defendants violate 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval under 21 U.S.C. § 355(i).

6. Upon entry of this Decree, Defendants and each and all of their owners, directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise are permanently restrained and enjoined under 21 U.S.C § 332(a), and the inherent equitable authority of this Court, from directly or indirectly manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any drug or dietary supplement at or from 1568 S River Rd., St.200, St. George, UT 84790, or at or from any other location(s) at which Defendants, now or in the future, directly or indirectly manufacture, prepare, process, pack, label, hold, and/or distribute any drug or dietary supplement (“the Establishment”),

unless and until:

A. Defendants retain, at Defendants' expense, an independent person (the "DS CGMP Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to inspect the Establishment to determine whether Defendants' methods, processes, and controls used to receive, document, investigate, and review and approve findings and follow up actions for complaints (the "Complaint Handling Program") are operated and administered in conformity with Dietary Supplement CGMP. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the DS CGMP Expert within ten (10) business days of retaining such expert or, if such Expert has already been retained upon entry of this Decree, within ten (10) business days after entry of this Decree;

B. The DS CGMP Expert performs a comprehensive inspection of the Complaint Handling Program and certifies in writing to FDA that they have inspected the Complaint Handling Program and that the Complaint Handling Program is, in the DS CGMP Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The DS CGMP Expert's report of the inspection, which shall be submitted to FDA no later than ten (10) business days after the inspection is completed and shall include, but not be limited to, a determination that Defendants have methods, processes, and controls to ensure that they:

- i. Establish and follow written procedures for reviewing and investigating product complaints, as required by 21 C.F.R. § 111.553; and
- ii. Document and investigate all complaints as required by 21 C.F.R. § 111.560 and 21 CFR § 111.570;

C. Defendants retain, at their expense, an independent person or persons (the "Labeling Expert"), who may be the same person as the DS GMP Expert, who is without personal or

financial ties (other than the retention agreement) to Defendants and/or their families, and who by reason of background, training, education, or experience, is qualified to inspect the Establishment and to review the representations Defendants make for each of their products on product labels; labeling; websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, www.balanceofnature.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants); promotional materials; and any other media over which Defendants have control. Defendants shall notify the FDA in writing of the identity and qualifications of the Labeling Expert within ten (10) business days of retaining such expert or, if such Expert has already been retained upon entry of this Decree, within ten (10) business days after entry of this Decree; and

D. The Labeling Expert shall submit a written report (“the Labeling Report”) certifying to FDA that:

i. The Labeling Expert has identified all of Defendants’ products and reviewed Defendants’ representations for each product on product labels; labeling websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, www.balanceofnature.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants); promotional materials; and any other media over which Defendants have control;

ii. Defendants have removed all representations, if any, that cause any of Defendants’ products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g), for indications for which they do not have FDA approval or, alternatively, that Defendants have obtained an approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for their products; and

iii. Based upon the Labeling Expert’s inspection and review, Defendants are no

longer causing any of their products to be drugs within the meaning of the Act for indications for which they do not have FDA approval. The Labeling Expert's written certification shall include the specific results of his or her inspection and review, including references to product names and copies of all materials reviewed;

E. Should the Labeling Expert identify any deficiencies in the Labeling Report as described in Paragraph 6.D:

- i. Defendants shall report to FDA and the Labeling Expert in writing the actions they have taken to correct such deficiencies; and
- ii. The Labeling Expert shall certify in writing to FDA, based upon the Expert's further review and/or inspections(s) that Defendants have removed all representations from each of their product labels; labeling; websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, www.balanceofnature.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants); promotional materials; and any other media over which Defendants have control, that cause any of Defendants' products to be drugs within the meaning of the Act for indications for which they do not have FDA approval;

F. FDA representatives may inspect the Establishment to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with this Decree, the Act, and its implementing regulations;

G. Defendants have reimbursed FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with Paragraph 6, at the rates set forth in Paragraph 15; and FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in Paragraphs 6.A-F of this Decree. In no circumstance shall FDA's silence be construed as a

substitute for written notification.

7. Upon resuming operations after complying with the requirements of Paragraph 6 and receiving FDA's written notification pursuant to Paragraph 6.G, Defendants shall retain an independent person or persons who shall meet the criteria for, and may be the same person as the DS CGMP Expert and/or Labeling Expert (hereinafter, the "Auditor"), to conduct audit inspections of the Complaint Handling Program, and of Defendants' dietary supplement labeling including product labels; labeling; leaflets; websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, www.balanceofnaute.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants); promotional materials; and any other media over which Defendants have control. Such audit inspections must entail the Auditor's physical presence at the Establishment; audit inspections may not be conducted entirely by virtual means (*e.g.*, by camera or videolink) without FDA's prior approval. After the auditor is retained, audit inspections under this Paragraph shall commence no less frequently than once every six (6) months for the first year thereafter and then no less frequently than once a year thereafter for the next four (4) years. The first audit shall occur not more than six months after entry of this Decree.

8. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants' Complaint Handling Program and dietary supplement labeling are in compliance with this Decree, the Act, and its implementing regulations and identifying any deviations from such requirements ("Audit Report Observations"). Each Audit Report shall contain a written certification that the Auditor personally inspected the Complaint Handling Program and Defendants' dietary supplement labeling including product labels; labeling; leaflets; websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, www.balanceofnaute.com, and any future

website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants); promotional materials; and any other media over which Defendants have control, and determined that Defendants' Complaint Handling Program and Defendants' dietary supplement labeling are in compliance with this Decree, the Act, and its implementing regulations. As part of every Audit Report, the Auditor shall assess the adequacy of actions taken by Defendants to correct any previous Audit Report Observations. Defendants shall maintain the Audit Reports in separate files at the Establishment and shall promptly make the Audit Reports available to FDA upon request.

A. Defendants shall ensure that the Audit Reports are delivered contemporaneously to Defendants and FDA by courier service, overnight delivery service, or electronic delivery, no later than ten (10) business days after the audit inspection is completed.

B. If an Audit Report contains any observations indicating that Defendants' Complaint Handling Program and dietary supplement labeling are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall, within twenty (20) business days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations will take longer than twenty (20) business days, Defendants shall, within fifteen (15) business days of receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within twenty (20) business days of the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is

necessary, or within the time period provided in an Audit Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within ten (10) business days of beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

9. Upon entry of this Decree, Defendants, and all of their owners, directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements), as defined by 21 U.S.C. § 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of the current good manufacturing practice regulations for dietary supplements set forth in 21 C.F.R. Part 111;

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered, into interstate commerce drugs, within the meaning of 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use;

C. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, within the meaning of 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval; and

D. Failing to implement and continuously maintain the requirements of this Decree, the Act, and its implementing regulations.

10. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection; a review of product labels, labeling, leaflets, websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, www.balanceofnature.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants), promotional materials, and any other media over which Defendants have control; a report prepared by the DS CGMP Expert, the Labeling Expert or the Auditor; or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of their noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

- A. Cease manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any or all products;
- B. Recall, at Defendants' expense, any product that is adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations;
- C. Revise, modify, expand, or continue to submit any reports, plans, procedures or other records prepared or required pursuant to this Decree;
- D. Submit additional reports or information to FDA as requested;
- E. Institute or reimplement any of the requirements set forth in this Decree;
- F. Issue a safety alert; and/or
- G. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

The provisions of this Paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor recalls and other corrective actions, at the rates specified in Paragraph 15.

11. The following process and procedures shall apply when FDA issues an order under paragraph 10, except as provided in Subparagraph D below:

A. Unless a different time frame is specified by FDA in its order, Defendants shall, within ten (10) business days after receiving such order, notify FDA in writing that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this Paragraph shall be made in accordance with the terms set forth

in Paragraph 23 of this Decree.

D. The process and procedures set forth in Paragraph 11.A.-C. shall not apply to any order issued under Paragraph 10 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief.

12. Any cessation of operations or other action described in Paragraph 10 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. Defendants may submit to FDA a written request to resume operations. Within forty-five (45) business days after FDA's receipt of a written request to resume operations, FDA will notify Defendants in writing whether Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations and whether they may resume operations. In no circumstance shall FDA's silence be construed as a substitute for written notification.

13. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' operations and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and all applicable regulations. During such inspections, FDA representatives shall be permitted to have immediate access to the Establishment, including, but not limited to, all buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material therein; take photographs and make video recordings; take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material; and examine and copy all records relating to the receipt, manufacture, preparing, processing, packing, repacking, labeling, holding, and distribution of any and all of Defendants'

products and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

14. Within fifteen (15) business days after FDA's request for Defendants' product labels; labeling; leaflets; websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, www.balanceofnature.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants); promotional materials; and any other media over which Defendants have control, Defendants shall submit a copy of the requested materials (in hard copy and electronic format) to FDA at the address specified in Paragraph 20.

15. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, including all transportation and associated costs for FDA investigators and experts, at the standard rates prevailing at the time costs are incurred. Defendants shall make payment to FDA within twenty (20) business days after receiving an electronic invoice for payment, which shall be sent to lex.howard@bonadmin.com. Defendants shall make payment through the Pay.gov electronic billing system, subject to all interest, fees, and penalties applicable to delinquent payments, in accordance with 31 U.S.C. § 3717 and 45 C.F.R. § 30. As of the date that this Decree is signed by the parties, these rates are: \$110.59 per hour or fraction thereof per representative for inspection and investigative work; \$132.56 per hour or fraction thereof per representative for analytical or review work; \$0.65 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses, where necessary. In the event that the standard rates for FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court. Defendants

shall notify FDA within fifteen (15) business day if the email address at which Defendants receive electronic invoices changes.

16. Within ten (10) business days after the entry of this Decree, Defendants shall post a copy of this Decree in a common area at the Establishment, at any other location at which Defendants conduct business, and on all websites under Defendants' control (including, but not limited to, www.balanceofnature.com, and any future website(s) under Defendants' control), and shall ensure that the Decree remains posted for as long as it remains in effect. Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this Paragraph.

17. Within ten (10) business days after the entry of this Decree, Defendants shall provide a copy of the Decree by personal service, certified mail, or electronic delivery (return receipt requested) to each and all of their owners, directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them (collectively, "Associated Person(s)"). Within twenty (20) business days after the date of entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this Paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

18. In the event that any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall, within fifteen (15) business days after the commencement of such association, provide a copy of this Decree, by personal service, certified mail, or electronic delivery (return receipt requested), to such Associated Person(s), and provide to FDA an affidavit stating the fact and manner of compliance with this Paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Decree pursuant to this Paragraph.

19. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of the company, or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this Paragraph no later than ten (10) business days prior to such assignment or change in ownership.

20. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked “Consent Decree Correspondence – Evig – [Topic],” shall reference this civil action by case name and civil action number, and shall be addressed to the Program Division Director, Office of Human and Animal Food Operations West 4 (HAFW-4), Denver District Office, U.S. Food and Drug Administration, 6th Avenue and Kipling Street, P.O. Box 25087, Building 20-DFC, Denver, Colorado 80225-0087 or via email at orahafwest4firmresponses@fda.hhs.gov.

21. Should Defendants fail to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: Two Thousand Dollars (\$2,000.00) in liquidated damages for each day such violation continues; an additional sum of Two Thousand Dollars (\$2,000.00) in liquidated damages per day, per violation for each violation of this Decree, the Act, and/or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any distributed dietary supplements or drugs that are unapproved, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations. Defendants understand and agree

that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

22. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), investigational and analytical expenses, expert witness fees, and court costs relating to such contempt proceedings.

23. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

24. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.


SO ORDERED:


Dated this _____ day of _____, 2023.

UNITED STATES DISTRICT JUDGE

We hereby consent to entry of the foregoing Decree:

FOR DEFENDANTS:


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and on behalf of EVIG, LLC DBA
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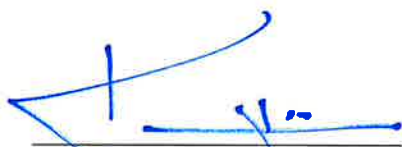
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